



K932330

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Attachment VI: Summary of Safety and Effectiveness Information [510(k) Summary]

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Device: Synthes Titanium-6Aluminum-7Niobium Unreamed Tibial Nail, as compared to Synthes Unreamed Tibial Nail (stainless steel).

Synthes Titanium-6Aluminum-7Niobium Unreamed Tibial Nail is intended for use in stabilizing fractures of the tibia. It is available in diameters of 8mm - 9mm, and lengths from 255mm to 420mm. The nail has a proximal angulation of 9° in the sagittal plane; it allows for interlocking with locking bolts.

Synthes Unreamed Tibial Nail is also indicated for fractures of the tibia.

To facilitate insertion and anatomic fit, the Unreamed Tibial Nail was modified (e.g., locking hole number/placement, material) to make the Titanium-6Aluminum-7Niobium Unreamed Tibial Nail.

The method used to sterilize the Synthes Titanium-6Aluminum-7Niobium Unreamed Tibial Nail is gamma radiation, as recognized by the United States Pharmacopeia.

The method used to validate the sterilization cycle was the Biological Indicator - Overkill Method for Low Bioburden Medical Devices per guidelines established by the Association for Advancement of Medical Instrumentation (AAMI). Synthes applied the guidelines appearing in "Process Control Guidelines for Gamma Radiation Sterilization of Medical Devices," AAMI, October 18, 1991.

The AAMI Biological - Overkill Method dictates a sterility assurance level in excess of 10^{-6} which assures a 12 logarithmic reduction in a possible micro-organism population.

The packaging system used to maintain device sterility consists of two sealed trays, one within the other, providing a double sterility barrier. The packaging trays and lids are manufactured from industry accepted components for EO and gamma radiation, namely, medical grade, blue tint, 6763 PETG plastic for the trays and Tyvek 1073 B for the lids. The sealed trays are placed in a paperboard shipping carton and shrink wrapped.

The radiation dose used to insure sterility basis, is 2.5 - 3.2 MegaRads. The validation minimum dose range, per AAMI, is 1.8 - 2.6 MegaRads.